

REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 5, 7 and 8 have been amended herein, and claims 1-4, 6, 9, 10 and 23-41 have been canceled without prejudice to continued prosecution.

Claims 5, 8, 11-13 and 18-20 are currently pending, and claims 7, 14-17, 21 and 22 stand withdrawn. Reconsideration of the pending application is respectfully requested.

Objections to the Specification

The Examiner objected to the paragraph of related applications on page 1 as being incomplete. Applicants have amended this paragraph to refer to U.S. Patent No. 6,680,294, which issued from U.S. Application No. 10/209,169. In view of this amendment, Applicants respectfully request that the objection to the specification be withdrawn.

The 35 U.S.C. §112 Rejections

Claims 5 and 8 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. According to the Examiner, the term “derivative” is a relative term that renders claim 5 indefinite. The Examiner further asserted that “derivative” does not particularly point out the degree and/or type of derivation that a given compound may have in relation to the parent compound and still be considered a “derivative.” This rejection is respectfully traversed.

Without acquiescing to the Examiner's rejection and simply to expedite prosecution, Applicants have amended claim 5 to remove the references to derivatives. Claim 5 now refers to “a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine or b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide.” Support for an ‘ester’ and an ‘amide’ of beta-alanine’ can be found, for example, at paragraph [0020] of the published application and support for di-peptides can be found, for example, at paragraph [0008] of the published application. In view of the amendments herein to claim 5, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 5 and 11-13 stand rejected under 35 U.S.C. §102(e) as being anticipated by Michaelis et al. (U.S. Patent 5,561,110), which, according to the Examiner, discloses pharmaceutical compositions comprising a beta-alanine dipeptide such as carnosine, and insulin. Applicants respectfully traverse this rejection with respect to the pending claims.

Without acquiescing to the Examiner's rejection, Applicants have amended claim 5 to remove the references to an insulin, an insulin mimic or an insulin action-modifier. Therefore, independent claim 5 is directed toward a composition that includes glycine and "a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine and an amide of a beta-alanine or b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide." In view of the amendments and remarks herein, the pending claims are not anticipated by Michaelis et al., and Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

The 35 U.S.C. §103 Rejections

Claims 5, 8, 11-13 and 18-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Michaelis et al., which is discussed above; claims 18-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rihova et al (U.S. Patent No 6,071,888), which teaches pharmaceutical compositions such as tablets, powders, drinking liquids, suppositories and informs suitable for injection that comprise beta-alanine. These rejections are respectfully traversed with respect to the pending claims.

As indicated herein, Applicants have amended the claims to refer to a composition that includes glycine and "a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine and an amide of a beta-alanine or b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide." Neither Michaelis et al. nor Rihova et al. suggest or propose that beta-alanine (or esters or amides thereof) or a di-peptide that includes beta-alanine can be combined with glycine. In view of the amendments and remarks herein, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. §103(a) be withdrawn.

Double Patenting

Claims 5, 8, 11-13 and 18-20 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 22-31 of U.S. Patent No. 6,426,361.

Applicants respectfully request that this rejection be held in abeyance until allowable subject matter is found. At that time, Applicant will submit an appropriate Terminal Disclaimer.

Request for Rejoinder

Claims 6, 7, 14-17, 21 and 22 were withdrawn as directed to a non-elected species following the Restriction Requirement of January 5, 2007 and Applicant's election of July 5, 2007. Since claim 5 should be allowable in view of the remarks herein, Applicants respectfully request that withdrawn claims 7, 14-17, 21 and 22 be rejoined and allowed pursuant to MPEP §806.04.

CONCLUSION

Applicants respectfully request that claims 5, 7, 8 and 11-22 be allowed. The Examiner is invited to call the undersigned Agent at the telephone number below if it is thought that this may advance prosecution of this application. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

/March 21, 2008/

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Date: _____

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